

5



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,268	09/29/2003	Michael Fantuzzi	33503/US	3101

7590 06/28/2005

Scott D. Rothenberger
DORSEY & WHITNEY LLP
Intellectual Property Department
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498

EXAMINER

KOSSON, ROSANNE

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,268	FANTUZZI, MICHAEL	
	Examiner	Art Unit	
	Rosanne Kosson	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,18-20,22,23 and 25-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,5-15,18-20,22,23 and 25-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Upon reviewing the wealth of prior art in the area of nutraceuticals containing coenzyme Q-10 (co-Q) and various other antioxidants, as well as issues raised in the instant application, the Examiner has determined that additional restriction of the claims is necessary. See, for example, Garti et al. (US 2003/0232095), which discloses a composition comprising co-Q solubilized in limonene and a carrier (see paragraphs 40-42 on p. 6).

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 5-10, 28, 31, 14, 15, 18, 19, 22, 23, 25-27, 32-38, 41, 42-48 and 51, drawn to a composition, or a soft gelatin capsule, or the gelatin capsule's packaged nutraceutical formulation, comprising coenzyme Q-10 and vitamin E, classified in class 424, subclass 94.4.
- II. Claims 1, 2, 5-9, 11, 28, 29, 14, 15, 18, 19, 22, 23, 25-27, 32-39, and 42-49, drawn to a composition, or a soft gelatin capsule, or the gelatin capsule's packaged nutraceutical formulation, comprising coenzyme Q-10 and a seed oil, classified in class 424, subclass 94.4.
- III. Claims 1, 2, 5-9, 12, 28, 30, 14, 15, 18, 19, 22, 23, 25-27, 32-38, 40, 42-48 and 50, drawn to a composition, or a soft gelatin capsule, or the gelatin capsule's packaged nutraceutical formulation, comprising coenzyme Q-10 and a fish oil, classified in class 424, subclass 94.4.

Art Unit: 1651

- IV. Claims 1, 2, 5-9, 13, 28, 14, 15, 18, 19, 20, 22, 23, 25-27, 32-37 and 42-47, drawn to a composition, or a soft gelatin capsule, or the gelatin capsule's packaged nutraceutical formulation, comprising coenzyme Q-10 and an antioxidant, classified in class 424, subclass 94.4.

The inventions are distinct, each from the other because of the following reasons.

The inventions of Groups I-IV are related as compositions comprising coenzyme Q-10 (co-Q) and a quantity of limonene sufficient to solubilize the co-Q. But the invention of each group also comprises a different nutraceutical, each of which has its own functions, therapeutic effects and considerations in the preparation of a composition. As a result, each of these inventions is patentably distinct.

Additionally, the search for any one group is not coextensive with the search required for any other group, thereby creating an undue burden of search and examination. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Further, the different groups have acquired a separate status in the art, as shown in part by their different classifications. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

Art Unit: 1651

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1651

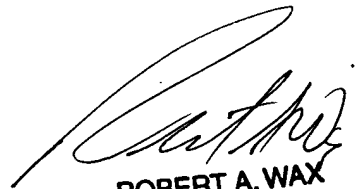
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2005-06-21



ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653